

DAG/TMH:jam 3/3/06 479831 S98014D
PATENTAttorney Reference Number 7158-71253-10
Application Number 10/648,631**REMARKS**

Claims 4, 5, 8, 9, and 19-36 are pending in this application. This Amendment will cancel claims 9, 19, 20, 22-24, 26, 27, and 29-31. Rejections of canceled claims are hereafter treated as moot. Applicants expressly reserve the right to pursue protection of any or all canceled subject matter in another application. This Amendment also will amend claims 4, 8, 25, 32, 35, and 36. Claim 4 will be amended to change the transitional language to "consisting of." Claim 8 will be amended to change the transitional language to "consisting of" and to incorporate the feature of claim 9. Claims 25, 32, 35, and 36 will be amended to incorporate the subject matter of allowable claims 21, 28, 33, and 34, respectively. No new matter is introduced by the foregoing claim amendments, and no new issues are raised.

Entry of the amendments after final action is appropriate because the amendments are believed to place the claims in a condition for allowance. Moreover, entry of the amendment would reduce the number of claims, remove the canceled subject matter from consideration and, thereby, simplify issues for appeal.

Upon entry of the foregoing claim amendments, **claims 4, 5, 8, 21, 25, 28, and 32-36 will be pending in this application.** Consideration of the claim amendments herein and reconsideration of the 35 U.S.C. §112, first paragraph rejection is requested.

Allowable Claims

Applicants thank the Examiner for indicating that claims 21, 28, 33, and 34 are allowable.

In-Person Interview:

Applicants thank Examiners Yao and Canella for the courtesy of an in-person interview with their representative, Tanya M. Harding, on December 8, 2005. Also present at the interview was Cynthia Kanik as an observer on behalf of a licensee of the technology described in the application. During the interview, the Amendment and Response to Non-Final Office Action, mailed to the Office on September 19, 2005 ("September 19th Response") was discussed.

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Applicants have received the Examiner's interview summary, dated January 3, 2006. Applicants thank Examiner Yao for providing the summary, but note the following inaccuracies for the record:

The interview was conducted in person at the Office and was not telephonic.

No copy of the interview summary was provided at the conclusion of the interview.

Information Disclosure Statement

Applicants thank the Examiner for considering and signing off on the Information Disclosure Statement ("IDS") mailed to the Patent Office (with Certificate of Mailing) on September 27, 2005. In the acknowledged copy of the IDS attached to the Office action, some of the lines connecting the Examiner's initials appeared broken; which could be (mis)interpreted to mean two of the listed references were not considered and initialed. To avoid possible future confusion, Applicants respectfully ask the Examiner to verify for the record that the following references from the IDS were considered and initialed:

1. Gavin *et al.*, "Histone H1 kinase activity, germinal vesicle breakdown and M phase entry in mouse oocytes." *J. Cell Sci.*, 107:275-283, 1994; and
2. Kohler and Milstein, "Continuous cultures of fused cells secreting antibody of predefined specificity." *Nature*, 256:495-497, 1975.

Rejections/Objections Withdrawn

Applicants thank the Examiner for withdrawing objections to the specification, for acknowledging that the pending claims have priority to U.S. Pat. App. No. 08/555,912, filed November 13, 1995, and for withdrawing several rejections under 35 U.S.C. §112, first paragraph, 35 U.S.C. §112, second paragraph, and 35 U.S.C. §102(b).

Claim Rejections under 35 U.S.C. §112, first paragraph:

Claims 22-25 and 30-32 have been rejected under 35 U.S.C. §112, first paragraph (new matter) because, allegedly, the "specification as filed . . . does not provide sufficient support for . . . WW and PPIase domains of Pin1 (SEQ ID NO: 2) fused to any heterologous polypeptide, or fused to a heterologous peptide consisting of an epitope tag, a carrier protein, a DNA binding

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domain, a transactivation domain, or an enzyme suitable for use as a label.” Applicants traverse this rejection.

“The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims” (*e.g.*, MPEP §2163, Section IIA 3(b)). In the instant case, the Office merely concludes that “specification as filed . . . does not provide sufficient support for . . . WW and PPIase domains of Pin1 (SEQ ID NO: 2) fused to any heterologous polypeptide, or fused to a heterologous peptide consisting of an epitope tag, a carrier protein, a DNA binding domain, a transactivation domain, or an enzyme suitable for use as a label,” and presents no evidence or reasoning to support this position. Based on this omission alone, the rejection should be withdrawn.

MPEP §2163 (*e.g.*, Section IB) states that “there is no *in haec verba* requirement, [and] newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” Even if the Office had supported its new matter rejection (which is not admitted), Applicants respectfully submit that the specification provides express, implicit, and inherent description of heterologous polypeptides (including, “an epitope tag, a carrier protein, a DNA binding domain, a transactivation domain, or an enzyme suitable for use as a label”) fused to the disclosed WW and/or PPIase domains.

The specification describes a “Pin1 polypeptide” as including “functional fragments of the polypeptide” (*e.g.*, at page 8, lines 26-28), such as the WW and/or PPIase domains. Explicit, implicit and inherent description of Pin1 polypeptides, such as the WW and/or PPIase domains, fused to the indicated heterologous polypeptides is provided, at least, as follows:

1. Epitope tag, such as HA, (His)₄ or (His)₆; see, *e.g.*, Figure 5 legend on page 6, Figure 6 legend on pages 6-7; page 14, lines 7-11; page 27, lines 24-25; page 29, line 1; page 30, lines 19-22; page 34, lines 25-25; page 36, lines 22-23; and/or page 37, line 17;
2. Carrier protein, such as keyhole limpet hemocyanin (KLH), thyroglobulin, bovine serum albumin (BSA), and tetanus toxoid; see, *e.g.*, page 15 lines 21-25;

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3. DNA binding domain or a transactivation domain, such as a GAL4 DNA binding domain or a GAL4 transactivation domain; see, *e.g.*, page 4, lines 14-19; Figure 2 legend at page 5; page 16, lines 10-15; page 17, lines 5-10; page 17, lines 20-22; page 18, lines 1-6; page 26, lines 7-8); Example 2 at pages 31-32; and/or page 33, lines 23-25; and
4. Enzyme suitable for use as a label; see, *e.g.*, page 20, lines 27-30; and/or page 32, lines 28-29.

The many foregoing examples (as well as others not specifically mentioned here) taken together demonstrate that the Applicants had possession of a genus of "heterologous polypeptides" fused to Pin1 polypeptides, including the WW and/or PPIase domains. Thus, the new matter prohibition of 35 U.S.C. §112, first paragraph should be satisfied with regard to claims reciting this genus. Nevertheless, merely to facilitate prosecution of this application, claims 25, 32, 35, and 36 as amended herein will recite the specific exemplary heterologous polypeptides listed above fused to particular WW or PPIase domains and the phrase "heterologous polypeptide" will be removed from the applicable claims.

Given the Office's assertion regarding new matter is unsupported by evidence or findings of fact and the specification clearly supports heterologous polypeptides (particularly, "an epitope tag, a carrier protein, a DNA binding domain, a transactivation domain, or an enzyme suitable for use as a label") fused to the disclosed WW and/or PPIase domains, Applicants respectfully submit that the disputed claims (particularly as amended herein) do not include new matter. Applicants request that this rejection be withdrawn.

Claims 4, 5, 8, 9, 19, 20, 22-27, 29-32, 35 and 36 have been rejected under 35 U.S.C. §112, first paragraph (written description) because, allegedly, "no metes and bounds can be determined for the terms 'comprising', or 'consisting essentially of' or 'a heterologous polypeptide.'" Applicants traverse this rejection; however, merely to facilitate prosecution of the present application, the disputed claims have been amended to remove the terms "comprising," "consisting essentially of," and/or "a heterologous polypeptide." Accordingly, this rejection is moot and Applicants request that it be withdrawn.

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Obviousness-Type Double Patenting

Claims 4, 5, 8, 9, and 19-32 have been rejected under the doctrine of obviousness-type double patenting in view of claims 1 and 2 of U.S. Patent No. 5,952,467. Applicants respectfully request deferral of this ground for rejection of until such time as all subject matter in the present application is indicated as allowable.

CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance. If it may further issuance of these claims, the Examiner is invited to call the undersigned at the telephone number listed below.

Respectfully submitted,

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